

Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed April 13, 2010. Currently, claims 1-14, 16-29, and 31-41 remain pending of which claims 11, 12, and 14 were previously withdrawn. Claims 1-10, 13, 16-29, and 31-41 have been rejected. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 1-10, 13, 16-21, 23-29, and 31-41 were rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch et al. (U.S. Patent No. 6,312,446), hereinafter Huebsch, in view of Hart (U.S. Patent No. 5,846,251) and Lafontaine et al. (U.S. Patent No. 5,964,782), hereinafter Lafontaine. After careful review, Applicant must respectfully traverse this rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). Initially it should be noted that there appears to be residual confusion regarding which state of Huebsch corresponds to an expanded position and which state corresponds to a contracted state. The Examiner’s attention is directed to, for example, claim 1 in which it is recited that the delivery position is the noncollapsed state having a generally conical configuration. The distal end of a collapse actuator is coupled to the distal aperture of the closure component (backing) and, when moved proximally solely by a collapse actuator, collapses the closure component to a generally disc shape collapsed state partially within the aperture to be closed. On the other hand, Huebsch appears to disclose a device having a delivery position which is a non-conical collapsed bi-cylinder which is urged to an expanded configuration no longer small enough to pass through the aperture in which it is deployed by the application of opposed proximal and distal forces supplied thereby forming a pair of opposed conical structures instead of a disc. In the absence of expansion, the device of Huebsch does not appear to be retained in the aperture to be closed. Confusion among terms “collapsed”, “non-collapsed”, and “expanded” is apparent in the discussion to date. While the device of Huebsch may

“collapse” longitudinally in forming the expanded bi-conical deployed state, there does not appear to be a collapsed delivery state having a generally conical shape and an expanded state having a generally disc shape. Instead the twin actuation members of Huebsch appear to move the collapsed cylindrical insertion state to a radially expanded bi-conical deployed state.

As acknowledged by the Examiner, “Huebsch et al. do not disclose the collapse actuator detachable distal end assuming a deformed profile solely in response to a sufficient proximal force applied to the collapse actuator in order to permit the detachable distal end to pass proximally through the distal aperture”. The distal end of the T-shaped or splined members do not appear to deform, but merely rotate to disengage.

In addition, a proximal force applied solely to either or both of outer shaft 146 or inner shaft 148 portions of mechanism 140, or to the pull mechanism 230, the collapse actuators of Huebsch, would appear to simply remove the device 100 from the body in its initially collapsed insertion state. Rather it is the combined proximal withdrawal of inner shaft 148 and the distal advance of outer shaft 146 (or presumably delivery catheter 40 which apparently must have an inner diameter greater than the embodiment depicted in Figs. 16 and 21 if that is the insertion state) which cooperate to symmetrically expand the device 100 about a body aperture positioned approximately halfway between the ends of the inserted cylinder.

If the embodiment of Figs. 16 and 21 spontaneously assume the configurations of those illustrations, it does not do so “solely in response to a sufficient proximal force applied to the collapse actuator” as recited in the claims. In the alternative, if the embodiment remains collapsed in the absence of an applied force, there must be an element which resists the distal motion of proximal end 214 and thus activation does not appear to be solely as the result of proximally directed force applied to the collapse actuator in any embodiment of Huebsch. In the device of the invention, the proximal end is held by the tissue engaging hooks and thus proximal motion of the collapse actuator suffices to collapse the cone to a disk without the presence of an actuation element which applies a distally directed force.

Any modification of Huebsch which relies solely upon a proximal withdrawal of an actuating element would appear to render the device of Huebsch unsatisfactory for its

intended purpose of symmetrically activating symmetrically opposed retention elements (see MPEP § 2143.01 Part V.) and to impermissibly alter the principle of operation of Huebsch which depends upon simultaneous proximal and distal activation forces to effect symmetrical expansion of proximal and distal portions of the aperture closure mechanism. (See MPEP § 2143.01 Part VI.) Indeed, the principle of operation of Huebsch appears to rely upon symmetrically disposed strut portions which span both sides of the septal defect and which are anchored by pressure applied to the tissue by the opposed proximal and distal struts. (Col. 4, lines 46-50.) Simply, a single sided device of Huebsch in which only the distal half is present and activated by proximal motion would not appear to be retained within the aperture given the absence of opposing struts and one of ordinary skill in the art would not be motivated to release such a device within the heart where Huebsch teaches that the device may be deployed.

As discussed previously, nowhere does Huebsch appear to disclose:

“a closure component including a collapsible backing movable between a non-collapsed delivery position, in which the backing has a generally conical shape with a center portion of the backing distally spaced from a periphery of the backing, and a collapsed deployed position, in which the backing center portion is collapsed proximally toward the backing periphery to have a generally disc shape, and a plurality of fibrous tissue engaging members disposed on the backing and oriented in a non-engaging orientation when traveling in a distal direction and in an engaging orientation when traveling in a proximal direction, the fibrous tissue engaging members entangling the backing when the backing is in the collapsed position”

as recited in claim 1. Instead, the device of Huebsch appears to be free of a backing and has a collapsed delivery position in which it assumes the generally cylindrical form of, for example, Fig. 2 and a generally bi-conical expanded deployed position of Fig. 4, thereby inverting each of the corresponding characteristics of the claimed device. Were the device of Huebsch to be deployed in the non-collapsed bi-conical configuration, the only configuration in which it has a conical component, it would appear to tear an opening in the tissue in which it is to be deployed which opening would be several times the dimensions of the existing aperture which it is intended to repair and thus one of ordinary skill in the art would not be motivated to employ the device in that insertion configuration. Were one to reduce the size of the conical portion to the size of the

opening through which it is to be deployed, it would appear to be incapable of engaging the wall adjacent to the aperture which has a dimension larger than that of the conical device, again rendering it unsatisfactory for its intended use. Were the tips of some of the struts to engage the tissue, blood would appear to flow freely through the gaps between the struts again rendering the modified device unsatisfactory for its intended purpose of plugging the aperture.

Huebsch does not appear to disclose a backing in the ordinary meaning of that term: "something forming a back" (Merriam-Webster's Online Dictionary, 11th Edition). Although the Examiner has asserted that the catheter delivered device, shown generally at 200, which comprises a cylindrical shaft 212 having a proximal end 214, a distal end 216, and a central portion 218, is a backing, there appears to be no support for the assertion within the disclosure of Huebsch. In discussing the disclosure of Lafontaine, the Examiner has acknowledged that Huebsch lacks the collapsible backing being made of pile or fabric, wherein the pile tissue engaging hooks engage portions of the pile backing to retain the pile backing in the collapsed position. To provide a "backing" as the term is used in the claims and as it would be interpreted by one of ordinary skill in the art in view of the specification, the cylindrical shaft would have to include at least a "backing center portion" said center portion being "distally spaced from a periphery of the backing" in the conical delivery position. The device of Huebsch does not appear to have a conical delivery position. That same unspecified center portion would have to assume "a generally disc shape" when collapsed toward the backing periphery.

Instead, the "cylindrical shaft 212" appears to have generally a cylindrical delivery position rather than a conical shape and there appears to be no portion of the cylindrical shaft 212 which could be designated as the distally spaced center portion which may be collapsed proximally toward a periphery of the cylindrical shaft 212. To the extent that the cylindrical shaft 212 has a "center portion", it would appear to be center 218 which remains static within the aperture during expansion of the device and does not appear to collapse to a disc, otherwise alter shape, or move toward the periphery of the struts which move radially outward away from it.

Although the Examiner has posited that hooks 270 of Huebsch are "proximally facing tissue engaging hooks", it is apparent that the hooks, which are disposed

perpendicular to the cylindrical shaft 212 in the collapsed cylindrical configuration which it assumes while being inserted in a distal direction, would be positioned to engage the tissue of the aperture when moving distally therethrough rather than being non-engaging. Further, since the hooks 270 extend perpendicularly from the surface of the struts 222, there appears to be no possibility that the hooks 270 entangle the struts 222, said to correspond to the backing, from which they extend and, as seen in Fig. 22, or alternatively as element 70 of Figs. 24, they are incapable of reaching through the intervening tissue to entangle the opposed surface of proximal struts 220 or even reaching the distally facing hooks 270, 70 of the proximal struts. The gap between opposed hooks at their closest approach (Figs. 22 and 24) appears to be one to two times the length of the hooks depending on the embodiment.

Furthermore, nowhere does Huebsch appear to disclose: “a collapse actuator releasably coupled to the collapsible backing, the actuator having a detachable distal end that is received within a distal aperture in the closure component and extends distal to the distal aperture when the closure component is in the non-collapsed position”. As will be seen in Figs. 5A, 5B, 6, and 9, as well as arguably in Figs. 16, 17, 21, and 22, the twist-loc mechanism 140 does not appear to extend distal to the distal aperture, if one is present, and any incidental distal protrusion beyond distal end 216 is not necessarily present in any of the illustrated embodiments and so is not inherent to the operation of Huebsch. As noted above, there is no element corresponding to the backing of claims 1 and 33, or the pile of claim 26, in the disclosure of Huebsch and thus Huebsch does not appear to disclose a collapse actuator releasably coupled to a collapsible backing.

Turning to Hart in an attempt to overcome the deficiencies of Huebsch, the Examiner makes reference to a collapse actuator, presumably obturator assembly 34, having an obturator expandable cone 54, mounted between solid cone 99 and the proximal portion 56 of the obturator end area 52. Both the obturator expandable cone 54 and expandable containment member 43 of Hart appear to be deployed in the collapsed configuration of Fig. 4 and upon activation assume an expanded, non-collapsed position of Fig. 6 in contrast to the structures recited in the claims which are deployed in a non-collapsed delivery position and which assume a collapsed position upon activation. Thus Hart does not appear to provide the collapse actuator acknowledged to be missing from

the disclosure of Huebsch. Instead of disclosing a collapse actuator, Hart appears to disclose an expansion actuator. While the actuator of Hart might appear to be suitable for expanding the initially collapsed delivery configurations of Huebsch, it does not appear to be capable of collapsing the initially non-collapsed conical backing of the claims solely in response to the application of a proximal force. The expanding actuator appears to be delivered in the collapsed configuration of Fig. 4 and if removable/removed is returned to that same configuration in Fig. 6 and so does not have a “deformed profile permitting the detachable distal end to pass proximally through the distal aperture”. The position of Fig 5 appears to be the only configuration in which element 54 is deformed and in that deformed state it cannot pass through the distal opening in the expanded, not collapsed, element 43. Thus the expanding actuator of Hart does not appear to overcome the acknowledged and identified deficiencies of Huebsch with respect to the actuator and/or the initial non-collapsed delivery position and deployed collapsed position of a conical backing which are recited in the claims.

The Examiner acknowledges that Huebsch lacks “the collapsible backing being made of pile or fabric wherein the pile tissue engaging hooks engage portions of the pile backing to retain the pile backing in the collapsed position” and turns to Lafontaine in an effort to overcome that deficiency. The ring shaped element 344 of Lafontaine depicted in cited Figs. 34A-C does not appear to overcome the lack of a backing in Huebsch, said backing having an initial conical shape with a center portion distally spaced from a periphery and a collapsed position having a generally disc shape. Instead, element 344 of Lafontaine appears to maintain a ring shape of varying outer diameter. Further, the radially outwardly disposed tissue engaging members of ring 344 do not appear to change orientation from a non-engaging orientation when traveling in a distal direction to a tissue engaging orientation when traveling in a proximal orientation as recited in the claims. Instead, they appear to be oriented radially while moving distally within the outer deployment sheath 380 of Fig. 36A. The radially outward orientation appears to be maintained as the ring is moved proximally. (Figs. 34A-C) Further, the structure and the action described at the cited col. 17, lines 38-43 and col. 18, lines 24-29 and illustrated in Figs. 34A-C does not appear to disclose “fibrous tissue engaging members entangling the backing when the backing is in the collapsed position”. Instead, it is the self-adhering

inner surface which adheres to itself and not the tissue engaging members which entangle with the backing. The tissue engaging members 366 appear to continue to be oriented radially outward while it is only separate inwardly directed hooks 370 which engage the interior pile 372 and so Lafontaine does not appear to disclose tissue engaging members 366 positioned to engage pile 372. (See hooks 370 and a plurality of pile elements 372 of Fig. 35 and col. 18, lines 16-17 and 24-29.)

For at least the reasons presented above, Huebsch in view of Hart and Lafontaine does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness and there appears to be no motivation to combine the elements of the references in the manner suggested by the Examiner. Doing so would appear to render Huebsch both unsatisfactory for its intended purpose of expanding both proximally and distally to secure a plug on both sides of an aperture and to alter impermissibly alter the principle of operation disclosed by Huebsch by substituting a single side device for a double sided one and by replacing both proximal and distal actuation means, which expand an initially contracted strut device, with a sole proximally directed force that contracts an initially expanded conical backing. Applicants respectfully request that the rejections of independent claims 1, 26, and 33 be withdrawn.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

Accordingly, claims 2-10, 13, 16-21, 23-25, 27-29, 31, 32, and 34-41, which depend from nonobvious independent claims 1, 26, and 33 respectively, also are believed to be nonobvious and Applicants respectfully request that the rejections be withdrawn.

Claim 22 was rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch in view of Hart, Lafontaine, and Luscombe et al. (U.S. Patent No. 5,683,418), hereinafter Luscombe. After careful review, Applicant must respectfully traverse this rejection.

Luscombe was cited for the purpose of providing a frangible connection between a collapse actuator having a distal end that is detachable from the distal end of a closure

component. Applicants note that independent claim 1 does not recite a frangible connection and thus Luscombe does not overcome a deficiency of Huebsch in view of Hart and Lafontaine as applied to claim 1. Accordingly claim 22, which depends from independent claim 1, also is believed to be nonobvious and Applicants respectfully request that the rejection be withdrawn.

With regard to the Response to Arguments, Applicants respectfully disagree with the Examiner's reasoning with respect to the force required to remove actuator 232 of Hart. Element 232 of Hart, a balloon catheter different from the most nearly corresponding element of the cited embodiments, is inserted in an undeformed state and advanced past the occluding material before it is expanded to the deformed state of the pending claims. In the deformed state it must be capable of passing proximally through the distal aperture associated with a collapsed backing member. As may be seen in Figs. 19 and 21, the deformed balloon catheter balloon is significantly (about 4 times) larger in diameter than the inner diameter of outer tube 231 through which it must pass in order to pass proximally through the (expanded, not collapsed) containment member 221. Further, the deformed balloon would have to pass through the vessel wall puncture and wound tract which are approximately half the diameter of the balloon 234 in its deformed state. Thus removal of the balloon proximally in the deformed state would appear to enlarge the area of the puncture wounds by a factor of approximately 4 which would be expected to cause significant tearing and tissue damage as well as requiring significant force to tear the tissue.

It is only in the undeformed state that the balloon 234 of Hart or the obturator cone 54 of Hart appears to be capable of passing proximally through the devices of Hart and the tissue and then only when the containment devices are in their expanded configurations as opposed to a collapsed position as recited in the pending claims. As noted by the Examiner, the balloon appears to be capable of being removed without affecting the outside diameter of the access device; however this is only the case when the balloon is in a nondeformed, deflated state. The claim recites that it is the "deformed profile permitting the detachable distal end to pass proximally through the distal aperture".

The balloon catheter 232 of Hart does not appear to provide an actuator, particularly not a collapse actuator. That function appears to be provided by element 223 and to the extent that balloon catheter 232 might be used for as an actuator, the deformed (inflated) balloon does not appear to be capable of passing through the access device. Applicants suspect that the Examiner may have intended to specify element 223 instead of balloon catheter 232; however a similar consideration applies. In the deformed (expanded) state element 223 is too large to be withdrawn through the access device through which it is inserted in an undeformed state. Pulling on the deformed element 223 is expected to result in damage as it is moved proximally through the much smaller puncture. It is the physical dimension of the element with respect to the dimension of the puncture which provides evidence of excessive pulling forces associated with either a deformed balloon or a deformed element 223.

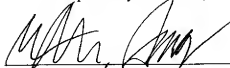
The Applicants acknowledge the Examiner's statement that tissue would appear to prevent proximal and distal hooks from contacting the pile. The Examiner's clarification that the proposed combination of Huebsch and Lafontaine was intended to place the pile/hook structure on the exterior surface of the device of Huebsch is appreciated. However this placement appears to be contrary to the teaching of Lafontaine in which the pile/hook structure engages on the interior surface of the ring thereby holding the ring closed. Also, the placement of the pile/hook structure on the exterior of the collapsed structure of Fig. 14 would place the hooks in a radially outward orientation about the cylindrical 200 during insertion where they would be expected to be tissue engaging when traveling in a distal direction through the tissue aperture. The pending claims recite that the fibrous tissue engaging members are "oriented in a non-engaging orientation when traveling in a distal direction". Note that the disclosure of Lafontaine appears to be that the radially outward orientation of the exterior hooks 346 is tissue engaging as illustrated in Fig. 34C.

In view of the foregoing, all pending claims are believed to be in condition for allowance. Further examination, reconsideration, and withdrawal of the rejections are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If

a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

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Respectfully submitted,



Glenn M. Seager, Reg. No. 36,926
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Glenn.Seager@cstlaw.com
Tel: (612) 677-9050